K073346

ziehm imaging

510(k) Summary MAR 21 2008

In accordance with the requirements of 21 CFR §807.92 the following summary of 510(k) safety and effectiveness information for the ZIEHM VISION^2 product family is being submitted.

Date:

March 4, 2008

Name of Submitter:

Ziehm Imaging, Inc.
4181 Latham Street
Riverside, CA 92501
Ph: (951) 781-2020
Fax: (951) 781-6457

Corresponding Official:

Richard L. Westrich,
Director of Regulatory Affairs

Device Proprietary Name (Commercial Names):

ZIEHM VISION^2 FAMILY;

ZIEHM VISION^2 FD

ZIEHM VISION^2 VARIO

ZIEHM VISION^2 VARIO FD

ZIEHM VISION^2 3D

ZIEHM VISION^2 FD 3D

Product Classification Name / Code:

System, X-Ray, Fluoroscopic, Image Intensifier,
Product Code: JAA, OWB, JAK
Regulation number: 892.1650

Common/Usual Names:

Digital Mobile C-Arm

Mobile Surgical C-arm

Biocompatibility:

The ZIEHM VISION^2 is not intended as a contact device, it does not need to be in contact with a patient to perform its intended use. However, the patient in some circumstance may touch or be contacted by the following areas of the device. Image Intensifier, Cable Harness, Radiation Grid, Image Intensifier Grid Retaining Ring, Painted Surfaces of the C-Profile and Generator Assembly. All patient contacting materials of the ZIEHM VISION^2 C-arm family are identical to the materials on our

existing Ziehm Vision C-arm devices, which are legally marketed devices (Ziehm Vision application K011292, Ziehm Vision FD application K 061534, and Ziehm Vario 3D application K061310).

Substantial Equivalence:

The ZIEHM VISION^2 product family of mobile c-arm products does not raise new questions of safety or effectiveness and is substantially equivalent to the following current legally marketed devises ZIEHM VISION, ZIEHM VARIO 3D and ZIEHM VISION FD

–	Ziehm Imaging,	ZIEHM VISION	K011292	Product Code JAA
–	Ziehm Imaging,	ZIEHM VISION FD	K061534	Product Code JAA
–	Ziehm Imaging,	ZIEHM VARIO 3D	K061310	Product Code JAA

The ZIEHM VISION^2 device family is a mobile C-arm x-ray system intended for fluoroscopic imaging and is a modified version of our present ZIEHM VISION digital mobile c-arm K011292. The modified ZIEHM VISION^2 incorporates additional new innovative technologies from two of our other legally marketed devices Ziehm Vision FD, and Ziehm Vario 3D. The base system includes high-voltage x-ray generator, and control, x-ray tube, image intensifier, touch control user interface and monitor cart/workstation with line power matching, Vision II 2D video image system with display, CAN bus control system, and internal and external image storage capabilities. The device includes functional options such as Endoscopic monitor display interface, 3D imaging, NaviPort digital image exchange interface, SSXI/Flat Panel Detector, and Vario Iso-centric operation. These options will be identified by extensions to the product name ZIEHM VISION^2 as Vario, FD, 3D, FD 3D.

Device Description:

Indications for Use

The ZIEHM VISION^2 product Family is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. At the discretion of a physician the device may be used for other imaging applications.

ZIEHM VISION^2 with option VARIO is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures and whenever the clinician benefits from variable Iso-centric positioning. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. At the discretion of a physician the device may be used for other imaging applications.

ZIEHM VISION^2 with option FD is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing

complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures and where higher accuracy in image geometry is required in and around high magnetic fields. At the discretion of a physician the device may be used for other imaging applications.

ZIEHM VISION^2 with option 3D is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures and Whenever the clinician benefits from variable Iso-centric positioning and/or intraoperatively generated 3D imaging of high contrast objects (bones and joints), complex anatomical structures such as cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image and c-arm positioning data is required for computer aided surgery procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. At the discretion of a physician the device may be used for other imaging applications.

User Characteristics

The ZIEHM VISION^2 product includes high-voltage x-ray generator and control, x-ray tube, image intensifier, and monitor cart/workstation with 2D image display and optional 3D digital image processing. Device provides internal and external image storage capability, and supports conventional spot-film capability with the Image intensifier option only. Optional monitor cart/workstation with NaviPort digital image exchange interface for Surgical Navigation Devices. Optional SSXI solid sate flat panel detector provides nearly distortion free imaging of critical anatomical structures. Optional Vario ISO-Centric mechanics work with the 3D imaging or stand alone as a method for track anatomical structures in both LAT and AP projections.

The device is intended for use by health care professionals such as physicians, orthopedic surgeons, vascular surgeons, neuro-vascular surgeons, cardiologists, radiologists and technologists in hospitals, outpatient clinics and other clinical environments. Ziehm Imaging anticipates the device will be used on a nearly daily basis. Ziehm Imaging applications specialists and/or qualified site personnel provide on site operator training in the proper use of the device.

General Description

The ZIEHM VISION^2 has two main units, Mobile Stand and Monitor Cart workstation.

The Mobile Stand C-arm consists of a High frequency generator and x-ray tube assembly with active cooling, x-ray control, virtual collimation assembly, 9" or 12" image intensifier (image receptor), VisionCenter user touch control interface, and CCD camera, mechanical C-Profile supporting the generator, image receptor and integrated laser light localizers. The c-profile in conjunction with the other mechanics of the mobile stand allow manual rotational, linear and vertical movements for positioning the c-arm at various angles and distances for visualization of patient's anatomical structures.

Mobile stand optional functionality includes, VARIO ISO-Centric motorized movement, VARIO-3D automated motorized control positioning for 3D imaging and Flat Panel Detector/SSXI (Image receptor) is available as a replacement for the standard 23cm/ 9" Image intensifier on the mobile stand.

Monitor Cart workstation consists of a mechanical assembly supporting dual flat panel LCD display monitors, line matching power supply, and Vision II digital image memory device. Optional functionality includes VisionCenter touch control, Vario 3D control and image processing, Ziehm NAVI PORT digital image exchange interface, Endoscopic monitor displays, external image storage and video connection for attachment of external monitor displays

Standards:

The ZIEHM VISION^2 Family of mobile x-ray devices will be tested and be shown to meet the appropriate requirements of the following standards prior to being marketed.

Federal Performance Standard for Diagnostic X-ray Systems 21 CFR 1020.30, 21 CFR 1020.31 and 21 CFR 1020.30

93/42/EEC - Annex II of EC directive of the Medical Devices Directive (MDD)

IEC 60601-1-3, Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment

IEC 60601-1-4, General requirements for safety, Programmable electrical medical systems.

IEC 60601-2-7, Medical Electrical Equipment, Safety of HV/X-ray Generators

IEC 60601-2-28 Medical Electrical Equipment Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis

IEC 60601-2-32, Medical Electrical Equipment, Safety of Associated X-ray Equipment

IEC60601-2-43, Particular requirements for the safety of X-Ray equipment for interventional procedures.

IEC 60825-1, Safety of laser products, Equipment Safety, requirements, and user guide

Conclusion:

The ZIEHM VISION^2 does not raise new questions of safety or effectiveness and is substantially equivalent to current legally marketed devices.

End of 510(k) Summary

Richard L. Westrich
Director Regulatory Affairs
Ziehm Imaging, Inc.
4181 Latham Street
Riverside, CA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Mr. Richaard Westrich
Director of Regulatory Affairs
Ziehm Imaging, Inc.
4181 Latham Street
REIVERSIDE CA 92501

Re: K073346
Trade/Device Name: Ziehm Vision^2 Family (Ziehm Vision ^{2}, Ziehm Vision^2 VARIO, Ziehm Vision ^{2} FD, Ziehm Vision^2 VARIO FD, Ziehm Vision^2 3D, Ziehm Vision^2 FD 3D)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, and JAK
Dated: March 4, 2008
Received: March 10, 2008

Dear Mr. Westrich:

This letter corrects our substantially equivalent letter of March 21, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

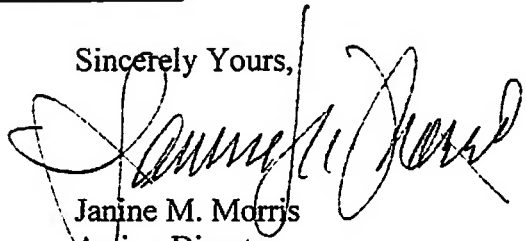
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

ziehm imaging

Indications for Use Statement

Applicant: Ziehm Imaging, Inc.

510(k) Number (if known): K073346

Device Name: ZIEHM VISION^2

Indications for Use: The ZIEHM VISION^2 product Family is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. At the discretion of a physician the device may be used for other imaging applications.

ZIEHM VISION^2 with option VARIO is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures. and whenever the clinician benefits from variable Iso-centric positioning. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. At the discretion of a physician the device may be used for other imaging applications.

ZIEHM VISION^2 with option FD is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures and where higher accuracy in image geometry is required in and around high magnetic fields. At the discretion of a physician the device may be used for other imaging applications.

ZIEHM VISION^2 with option 3D is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurological, critical care, and emergency room procedures and Whenever the clinician benefits from variable Iso-centric positioning

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and/or intraoperatively generated 3D imaging of high contrast objects (bones and joints), complex anatomical structures such as cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image and c-arm positioning data is required for computer aided surgery procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the Image Intensifier. At the discretion of a physician the device may be used for other imaging applications.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073346